Exhibit D

Article

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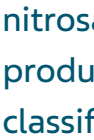
Teva api Adopts New Nitrosamine Regulations



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Senior Direcor, Global RA Teva api

Regulatory Affairs

In September, 2019, the EMA (European Medicines Agency) and EDQM (European Directorate of Quality of Medicines) published a document (EMA/189634/2019 and CMDh/404/2019) on their respective websites called, “Information on nitrosamines for marketing authorization holders”. It requested that marketing authorization holders (MAHs) “evaluate the risk of the presence of nitrosamine impurities in human medicinal products containing chemically synthesized active pharmaceutical ingredients”.

The background

In July, 2018, authorities in the EU became aware of the presence of nitrosamines in sartan active substances (APIs) with a tetrazole ring, produced by certain API manufacturers. These nitrosamines were classified as probable human carcinogens. This discovery prompted much action, including contacting CEP holders to request data and corrective actions, assessing responses to such requests, GMP inspections of manufacturing sites, suspension of CEPs, where appropriate, and their restoration after appropriate corrective actions had been implemented.

This then led to the September 2019 publication of the document, requiring all MAHs to follow an investigation process for all synthesized APIs (other than sartans with a tetrazole ring).

The 3-step approach

With the new regulations, MAHs and consequently, relevant API manufacturers, will need to take the following three steps with regard to all their synthesized APIs and fermentation products. The steps below describe the action plan from the API manufacturer’s perspective:

Step 1 – Risk evaluation: Companies should perform a risk evaluation of their chemically synthesized APIs with regards nitrosamine formation, using quality risk management principles.

Please note: The EDQM and EMA initially required this step to have been completed by March, 2020. It has now been revised to March, 2021. For Korea MFDs, this step needs to be completed by December, 2020.

Step 2 – Confirmatory testing: in the event that a risk of presence of nitrosamines is identified as a result of the risk evaluation, confirmatory testing should be carried out using appropriately validated and sensitive methods.

Step 3 – Revision to the DMF/CEP: Where nitrosamine impurities have been detected, DMF/ CEP holders should notify the customers for the relevant API and update the DMF/apply for a revision to their CEP application(s) in a timely manner to introduce any required changes, such as amendment of the manufacturing process or changes to specifications and introduction of controls.

Please note: The EDQM and EMA require that steps 2 and 3 be completed by September, 2022. For Korea MFDs, step 2 needs to be completed by December, 2021, and step 3 by December, 2022.

Our response

It's of utmost important to us that Teva api products are safe and of high-quality. As a result of the new regulations, we implemented the following steps:

- All synthetic products in our portfolio (for all markets) were assessed for risk of nitrosamine presence. We were ready in time for the March 2020 deadline (this deadline has now been moved to March, 2021).
- The products that were reviewed included commercial products, pre-launch products, and new products that are planned for submission in 2020-2021. Products were reviewed with full alignment to EMA instructions, covering all potential root causes for nitrosamines presence.
- Products that were identified as potential risks, were mapped as either high, medium, or low risk, based on the proximity between the two components – nitrosating source and amine source – during the production process.
- Based on this risk magnitude (high/medium/low risk), confirmatory testing was scheduled, and the planned timelines are with full adherence to EDQM and EMA demands.

Teva API CEPs

All Teva API CEPs, including for sartan products, are currently valid. Step 1 has been completed, and all information was provided to EDQM as requested, by March 26, 2020.

Future Products

In parallel to conducting this review for existing products, we have guided our development teams and adjusted internal SOPs and reports formats to ensure that, going forward, all our newly-developed APIs will be assessed in accordance with the current regulations.

About the author

Olga Progrebinsky has a Ph.D. degree in Organic Chemistry from Tel-Aviv University and has worked in Teva api's regulatory affairs group for 13 years and is currently the head of global regulatory affairs at Teva api. The Teva api global RA team is spread across 10 countries and provides regulatory support to all Teva api sites and all Teva api customers worldwide.

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